

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN**

Andrew Lyles, #667516

Plaintiff,

v.

Papendick et al

Defendants,

Case No.: 2:19-cv-10673

District Judge: Laurie J. Michelson

Magistrate Judge: Kimberly Altman

LAURENCE H. MARGOLIS P.C.

Ian Cross (P83367)

Attorney for Plaintiff

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**DEFENDANTS SHARON OLIVER, M.D. AND KEITH PAPENDICK,
M.D.'S MOTION FOR SUMMARY JUDGMENT**

EXHIBIT D

Affidavit of Randall R. Stoltz, M.D., C.C.H.P. (Correctional
Medicine)

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AFFIDAVIT OF RANDALL R. STOLTZ, M.D., C.P.I., C.C.H.P.

STATE OF INDIANA)
) SS
COUNTY OF VANDERBURGH)

I, Randall R. Stoltz, M.D., C.P.I., C.C.H.P., being first duly sworn, deposes and states:

1. My name is Dr. Randall Stoltz, M.D. I have been a licensed medical doctor since 1984. I am a certified correctional healthcare professional by the National Commission on Correctional Healthcare (NCCH), and am also board certified in family medicine.
2. I have over twenty-three (23) years of experience in correctional medicine. I have served as medical director of Vanderburgh County Detention Center in Evansville, Indiana since 1998, and as medical director of Warrick County Correctional Center in Booneville, Indiana since 2017. Additionally, I treated patients in my private family medicine practice from 1987 to 2005. I have also served as a volunteer faculty member of Indiana University School of Medicine for the past twenty-one (21) years. A copy of my curriculum vitae is attached.
3. Based upon my knowledge, skill, experience, training, and education, I am familiar with the medical conditions involved in Mr. Andrew Lyles' care and/or those alleged in the plaintiff's Complaint, including but not limited to gastrointestinal conditions, ulcerative colitis, lower abdominal pain, diarrhea, colonoscopies, fecal occult blood tests (FOBTs), rectal bleeding, constipation, and the care, treatment, and causes associated with said conditions.
4. I have been provided with, and have reviewed, the Complaint and medical records pertaining to the plaintiff, Andrew Lyles.

5. Based upon the records, Mr. Lyles first reported his gastrointestinal issue on or about November 7, 2016, including a 3-week history of abdominal pain and occasional blood in his stool. From November 7, 2016 through August 2017, Mr. Lyles received appropriate medical treatment from the defendants for his symptoms and continued complaints, including but not limited to: FOBTs (two of which were positive in November 2016 and two of which were negative in February 2017), abdominal x-rays (which initially showed constipation), blood tests (which all showed no anemia), an anoscopy exam, a flexible sigmoidoscopy, Protonix (which blocks stomach acid and may help heal an ulcer), a colonoscopy following appropriate conservative treatment and appropriate investigation of other causes his symptoms, Balcalizide, oral Prednisone, intravenous fluids, and sending him to a hospital for further management.
6. Mr. Lyles was ultimately diagnosed with ulcerative colitis, was hospitalized in August 2017, and later underwent an abdominal colectomy in 2019.
7. The medical records demonstrate that Mr. Lyles was seen many times by Dr. Oliver, and she ordered appropriate laboratory testing, X-rays, and medications in a timely manner to treat his symptoms. There was no unreasonable delay of care.
8. The length of time until final diagnosis was reasonable in light of Mr. Lyles' symptoms and had no meaningful degree of influence on the outcome in this case.

Ulcerative colitis is not a preventable or curable condition, other than removing one's entire colon.

9. Dr. Papendick's decision to ATP the initial 407 colonoscopy requests was proper based on the facts and Mr. Lyles' presenting symptoms, testing, and lab work at that time. The initial X-rays showed constipation. Thus, it was reasonable to clear this first to see if this corrected the condition. Also, the lab work showed a normal blood count, which continued to be consistent with the effects of constipation as opposed to more serious conditions and suggested that a colonoscopy was not medically necessary on January 6, 2017. With a normal blood count, and later with improvements in Mr. Lyles' bowel movements and medication treatments given, it is reasonable to believe that Mr. Lyles' symptoms and the causes of his symptoms were consistent with other medical conditions which did not require a colonoscopy at that point.
10. After demonstrating improvement and positive response to treatment for a couple of months, Mr. Lyles' symptoms began to worsen and at that point Dr. Oliver submitted another 407 request for a colonoscopy, and it was appropriately approved by Dr. Papendick the next day on April 12, 2017.
11. GI/colonoscopy referral and appointment set up time can take a couple of months to get arranged, thus the timing of Mr. Lyles' colonoscopy after it was approved was not unusual, nor unreasonable.

12. The eventual diagnosis of ulcerative colitis was made and appropriate medication was prescribed. Mr. Lyles had a more severe flare-up and was sent to the hospital.
13. Based upon the medical records and Mr. Lyles' presenting symptoms, I do not agree that an earlier diagnosis of ulcerative colitis should have been made. I do not believe that Mr. Lyles suffered any damages as a result of the care, treatment, and decision-making provided by Dr. Oliver or Dr. Papendick.
14. I conclude with a reasonable degree of medical certainty that the care provided by Dr. Oliver was proper and showed no omission or delay based on the documentation in the medical records. The assessment, diagnoses, and treatment of Mr. Lyles' complaints and symptoms involved the exercise of medical judgment by Dr. Oliver.
15. In addition, Dr. Papendick used his medical judgment to decide at what point a colonoscopy was indicated and the records reveal a reasonable conservative medical management approach was done prior to the 407 approval.
16. I reserve my right to modify my expert opinion if new information becomes available.
17. The statements made in this affidavit are true and accurate to the best of my current knowledge, information, and belief.

Dated:

09 NOVEMBER, 2021



Randall R. Stoltz, M.D., C.P.I., C.C.H.P.

Subscribed and sworn to before me this

9 day of November 2021.

Jacqueline Wysong
Jacqueline Wysong, Notary Public
County of Bay
Acting in Florida
My Commission Expires: 10/21/2024



Randall R. Stoltz, MD, CPI, CCHP

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Employment/Work History

Advarra IRB, Non-affiliated, Scientific, Board Member – November 2018 – Present

- Reviews protocols and scientific information submitted for IRB approval

Vanderburgh County Detention Center, Evansville, IN, USA - 1998 – Present

Medical Director - 1998 - Present

- Develops and implements health care plans for inmates in the county detention center and works closely with local public agencies to develop ongoing care plans upon inmate release.

Warrick County Correctional Center, Boonville, IN - 2017- Present

Medical Director – 2017 - Present

- Develops and implements health care plans for inmates in the county detention center and works closely with local public agencies to develop ongoing care plans upon inmate release.

Covance Clinical Development Services, Evansville, IN, USA - 2005 – 2017

Medical Director, Medical and Pharmacy Staff - 2005 - 2017

- Provides supervision and direction to the physicians of the Covance Clinical Research Unit, as appropriate.
- Ensures that there is proper medical coverage from the physicians to cover the medical safety to the unit during all hours of operation.
- Provides medical consultation for clients on study design and safety for early clinical phases of drug development.
- Interfaces with the medical staff and clients to ensure proper study designs and notification of serious adverse events to the study sponsors.

West Pharmaceutical Services – GFI Research Center, Evansville, IN, USA - 1999 – 2005

Medical Director, Medical Staff - 1999 - 2005

- Was responsible for providing support, guidance and supervision to the medical staff.
- Reviewed protocols for feasibility, ensuring safety and welfare of volunteers; served as investigator and worked closely with study sponsors to ensure proper trial execution.

Indiana University School of Medicine, Indianapolis, IN, USA - 1990 – Present

Volunteer Faculty Member - 1990 - Present

- Serves as a preceptor to medical students, teaching Introduction to Clinical Pharmacology, Family Medicine, and Correctional Health Care

Private Practice – Family Medicine, Evansville, IN, USA - 1987 – 2005

Physician - 1987 - 2005

- Practiced family medicine, providing primary care for patients of all ages from infants to elderly.

GFI Pharmaceutical Services, Evansville, IN, USA - 1988 – 1999

Medical Director, Medical Staff - 1989 - 1999

- Was responsible for providing support, guidance and supervision to the medical staff.
- Reviewed protocols for feasibility, ensuring safety and welfare of volunteers; served as investigator and worked closely with study sponsors to ensure proper trial execution.

Medical Associate - 1988 - 1989

- Served as Investigator for clinical trials including all the responsibilities defined for that role.

University of Evansville, Evansville, IN, USA - 1986 – 2012

Medical Director, Student Athletic Training Program – 2001 – 2012

- Develops training courses to educate students in medical areas needed to meet accreditation standards.

Medical Director, Student Health and Wellness Center - 1986 - 2012

- Oversees medical care for students attending the University of Evansville.
- Assists in development of policies and procedures for admission and ongoing healthcare.

St. Mary's Medical Center, Evansville, IN, USA - 1985 – Present

Physician Staff Member, Department of Family Practice - 1985 - Present

- Responsible for complying with the hospital guidelines when caring for patients in the hospital.
- Works with hospital departments to develop ongoing process improvement.

Chairman, Department of Family Practice - 1994 - 2002

- Reviewed physician's credentials and applications to evaluate qualification for staff privileges.
- Handled hospital complaints about physicians in the department.
- Developed policies, procedures and Quality Assurance functions within the department.

Vice-Chairman, Department of Family Practice - 1993 - 1994

- Assisted the chairman with reviewing physician credentials and applications to evaluate qualification for membership.
- Assisted the chairman with hospital complaints about physicians within the department.

Deaconess Hospital, Evansville, IN, USA - 1987 – Present

Physician Staff Member - 1987 - Present

- Abides by hospital regulations for admission and care of patients at the hospital.

Evansville Protestant Home, Evansville, IN, USA - 1987 – Present

Medical Director - 1987 - Present

- Oversees medical care of nursing home residents

Heartland Rehabilitation Center, Evansville, IN, USA - 1999 – 2002

Utilization Review Committee - 1999 - 2002

- Reviewed rehabilitation records for accuracy and ensured that the records and care met general rehab standards.

Arbor Hospital, Evansville, IN, USA - 1992 – 1994

Governing Board Member - 1992 - 1994

- Worked with hospital administration to develop clinical operation policies and procedures to efficiently operate a psychiatric hospital.

Americare Living Center, Evansville, IN, USA - 1989 – 2005

Medical Director - 1989 - 2005

- Oversaw medical care of nursing home residents and intervened if nursing staff had problems with other physicians.
- Assisted with infection control and Quality Assurance functions.
- Worked to develop and improve nursing home policies.

Therapeutic Experience

- General medicine
- Correctional medicine

Language Capabilities

- English

Education

- Residency in Family Practice, St. Mary's Medical Center. Evansville, IN, USA
- MD Degree. Indiana University School of Medicine, Indianapolis, IN, USA
- B.S. Degree in Biology, University of Southern Indiana, Evansville, IN, USA

Memberships

- American Academy of Family Physicians
- Indiana Academy of Family Physicians
- Indiana State Medical Association
- Vanderburgh County Medical Society (past President and Board member)
- National Commission on Correctional Health Care (Surveyor)
- ACRP (Association of Clinical Research Professionals)--CPI Exam Committee
- ACPU (Association of Clinical Pharmacology Units)-- past Board Member

- ACCP (American College of Correctional Physicians)-- member
- ACHP (Academy of Correctional Health Professionals)-- member

Other

Licensure

- Physician License, State of IN, License No.01033825A
- DEA, License No. AS2892633

Certifications

- Board Certification in Family Medicine
- CPI (Certified Principal Investigator) through ACRP
- Certified Correctional Health Professional, NCCHC (National Commission on Correctional Healthcare)
- CITI training course in Human Subject Research Protection and GCP (Good Clinical Practice)

A list of publications, manuscripts, abstracts, and presentations is available upon request.

Randall R. Stoltz, MD, CPI, CCHP

Updated 1/01/2019

Appendix 1

Publications

- M. Hoch, B. Darpo, T. Remenova, **R. Stoltz**, M. Zhou, P. Kaufmann, S. Bruderer, J. Dingemanse Drug Design, Development and Therapy, "A thorough QT study in the context of an up titration regimen with selexipag, a selective oral prostacyclin receptor agonist" (Dec 2014)
- **Stoltz, R.R.**, Stockman, N., Hussey, E.K., Dobbins, R.L., O'Connor-Semmes, R., Kapur, A., Murray, S., Layko, D., and Nunez, D. (2008) Multiple-dose pharmacokinetics and pharmacodynamics of sergliflozin etabonate, a novel inhibitor of glucose reabsorption, in healthy overweight and obese subjects: a randomized double-blind study. *J. of Clinical Pharmacology*
- **Stoltz, R.R.**, Stockman, N., Hussey, E.K., Dobbins, R.L., O'Connor-Semmes, R., Kapur, A., Murray, S., and Nunez, D. (2007) A Double-Blinded Randomized Repeat Dose Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Three Times Daily Dosing of Sergliflozin, a Novel Inhibitor of Renal Glucose Reabsorption, in Healthy Overweight and Obese Subjects. *ADA 2007 Abstract*
- Abstract #96.026 "Low Incidence of Endometrial Hyperplasia and Bleeding in Women on 2 Years of Unopposed 0.3 mg Esterified Estrogens (Estratab®)"
- Renagel®, A Nonabsorbed, Calcium and Aluminum-free Phosphate Binder, Lowers Serum Phosphorus and Parathyroid Hormone
- Reduction of Serum Lactate by Sodium Dichloroacetate, and Human Pharmacokinetic-Pharmacodynamic Relationships. *Journal of Pharmacology and Experimental Therapeutics* 279. 686-293, 1996
- Efficacy and Safety of Low, Standard and High Dosages of an Estradiol Transdermal System (Estrim®) Compared with Placebo on Vasomotor Symptoms in Highly Symptomatic Menopausal Patients. *Publication C TS 17 930*, February 4, 1998
- Ineffectiveness of Neurokinin-1 Antagonist in Acute Migraine: A Crossover Study
- Safety, Tolerability, and Efficacy of the 0.8 mg Dose of Cerivastatin, a New HMG-CoA Reductase Inhibitor
- Short-Term Efficacy and Safety of Pravastatin in Hypercholesterolemic Women
- Lack of Effect of Multiple Dose Gatifloxacin (GAT) on Oral Glucose Tolerance (OGTT), Glucose and Insulin Homeostasis, and Glyburide Pharmacokinetics (PK) in Patients with Type II Non-Insulin Dependent Diabetes Mellitus (NIDDM)
- Effect of Multiple-Dose Gatifloxacin (GAT) or Ciprofloxacin (CIP) on Glucose Homeostasis and Insulin Production In-Patients with Non-Insulin Diabetes Mellitus (NIDDM) Maintained with Diet and Exercise
- Valsartan, a New Angiotensin II Antagonist for the Treatment of Essential Hypertension
- Gastric Emptying, Pulmonary Function, Gas Exchange, and Respiratory Quotient After Feeding a Moderate Versus High Fat Enteral Formula Meal in Chronic Obstructive Pulmonary Disease Patients. *Nutrition* Vol. 12, No.4, 1996
- Safety, Tolerability, and Pharmacokinetics of an Extended-Release Formulation of Fluvastatin Administered Once Daily to Patients with Primary Hypercholesterolemia. *Journal of Cardiovascular Pharmacology* Vol. 37, No. 5, 2001
- Pharmacokinetics and Pharmacodynamics of Peldesine (BCX-34), a Purine Nucleoside Phosphorylase Inhibitor, following Single and Multiple Oral Doses in Healthy Volunteers. *Journal of Clinical Pharmacology*, 2000; 40:410-420
- **Stoltz, R.R.**, Sansone-Parsons, A., Krishna, G., Simon, J., Soni, P., Kantesaria, B., Herron, J., "Effects of Age, Gender, and Race/Ethnicity on the Pharmacokinetics of Posaconazole in Healthy Volunteers," *Antimicrobial Agents and Chemotherapy* Vol. 51, No.2, p. 495-502, Feb. 2007
- Mathews Adera^a, Pol Boudes^a, Alexander Bragat^a, Sheela Sitaraman^a, Richard Lazauskas^a, Ken Valenzano^a, George Lankas^a, **Randall Stoltz^b**, Jane Royalty^b, Douglas Greene^a, "Pharmacokinetics and muscle distribution of AT2220, a pharmacological chaperone of acid-glucosidase, in healthy volunteers", ^aAmicus Therapeutics, Cranbury, NJ, USA, ^bCovance Inc., Princeton, NJ, USA; *Molecular Genetics and Metabolism* 102 (2011) S3-S47

- Daniel Spyker¹, James Cassella¹, **Randall Stoltz**², Paul Yeung³, “Inhaled loxapine and intramuscular lorazepam in healthy volunteers: a randomized placebo-controlled drug-drug interaction study”, Teva Pharmaceutical Industries Ltd., *Pharmacology Research & Perspectives*, 2015/Vol. 3/ Iss. 6/e00194
- B Darpo¹,... RR Stoltz¹⁵, “Results From the IQ-CSRC Prospective Study Support Replacement of the Thorough QT Study by QT Assessment in the Early Clinical Phase”, ¹⁵ Covance Clinical Research Unit, Evansville, IN, USA, Vol. 97 Number 4, April 2015, www.wileyonlinelibrary/cpt